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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/587,892	06/18/2007	Markus Muller	075422-0020	2347
20279 7590 03/17/2008 MCDERMOTT WILL & EMERY LLP 600 13TH STREET, N.W. WASHINGTON, DC 20005-3096				
EXAMINER				
CHUNDURU, SURYAPRABHA				
ART UNIT		PAPER NUMBER		
1637				
MAIL DATE		DELIVERY MODE		
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/587,892

**Applicant(s)**

MULLER ET AL.

**Examiner**

Suryaprabha Chunduru

**Art Unit**

1637

**Period for Reply** -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 28 July 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-22 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-22 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SF/86)
- Paper No(s)/Mail Date 6/18/07, 7/28/06
- 4) ☐ Interview Summary (PTO-413)
- Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

**DETAILED ACTION**

***Status***

1. Claims 1-22 are pending.

***Priority***

2. This application filed on June 18, 2007 is a 371 of PCT/EP05 /00693 filed on January 25, 2005, which claims foreign priority to EPO 04001864.0 filed on 01/29/2004.

***Information Disclosure Statement***

3. The information Disclosure Statement filed on June 18, 2007 and July 28, 2006 have been considered.

***Abstract of the Specification***

4. Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

The instant abstract is objected because it contains legal phraseology 'means'.

***Informalities***

5. The following informalities are noted.

- (i) Claim 1 recites steps in alphabetical order, in which step b) is repeated. Appropriate correction is required.

***Claim Rejections - 35 USC § 112***

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

A. Claims 21-22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 21-22 provide for the use of the method in claim 1, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claims 21-22 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

B. Claims 8-11, 18-19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The meets and bounds of the claims are unclear and indefinite because the step b) is repeated and the method does not comprise step a) and it is unclear what steps the instant claims refer to.

***Claim Rejections - 35 USC § 102***

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

A. Claims 1-2, 11-15, 17, 19-22 are rejected under 35 U.S.C. 102(b) as being anticipated by Thatcher et al. (US 5,981,735).

Thatcher et al. teach a method for the chromatographic separation of a nucleic acid mixture wherein plasmid DNA is separated from other components of the mixture, wherein the method comprises

(a) the nucleic acid mixture is adjusted with one or more alkali salts and/ or alkaline earth salts in aqueous solution to a conductance that is equivalent to a conductance of 70 mS to 95 mS at a pH of 4.8 to 5.4 at temperature of 20<sup>0</sup> C (see col. 15, line 50-56);

(b) the nucleic acid mixture is brought into contact with a chromatographic stationary phase (see col.15, line 56-67, col. 6, line 1-46);

(c and d) the stationary phase is then washed at least once with a solution comprising an alkaline earth salt in a concentration ranging from 100mM to 240mM based on pH of 7 to 7.4 and the plasmid DNA bound to the chromatographic stationary phase is subsequently eluted with a solution comprising an alkali earth salt in a concentration of 270mM or higher based on pH 7 to 7.4 (see col. 16, line 40-58, indicating appropriate ionic strength buffers are used based on pH 5 to 8 for wash and elution of plasmid DNA).

With regard to claims 11-13, Thatcher et al. teach that the wash and elution solutions comprise NaCl at concentration ranging from .1 to 1.5M based on pH 5 to 8.0 (see col. 16, line 47-58).

With regard to claims 14-15, Thatcher et al. teach that said chromatographic stationary phase is an anion exchanger that comprises dextran, agarose gel or any anion exchange matrices (see col. 15, line 49-67, col. 16, line 1-10).

With regard to claim 17, 19, Thatcher et al. teach that the method is carried out at room temperature and mixture of alkali salts and/or alkaline earth salts are used (see col.15, line 1-67, col. 16, line 1-58).

With regard to claim 20-22, Thatcher et al. teach nucleic acid mixture is a cleared lysate from prokaryotic cells and the method purifies plasmid DNA and the plasmid DNA is used for gene therapy or genetic vaccination (see col. 15, line 1-60, col. 21, line 54-67, col. 2, line 1-9). Accordingly the instant claims are anticipated.

B. Claims 1-15, 17-22 are rejected under 35 U.S.C. 102(b) as being anticipated by Aberin et al. (US 6,404,892).

Aberin et al. teach a method of claims 1, 17, for the chromatographic separation of a nucleic acid mixture wherein plasmid DNA is separated from other components of the mixture, wherein the method comprises

(a) the nucleic acid mixture is adjusted with one or more alkali salts and/ or alkaline earth salts in aqueous solution to a conductance that is equivalent to a conductance of 70 mS to 95 mS at a pH of 4.8 to 5.4 at temperature of 20<sup>0</sup> C (see col. 2, line 47-67, col. 3, line 1-13);

(b) the nucleic acid mixture is brought into contact with a chromatographic stationary phase (see col. 3, line 14- 44);

(c and d) the stationary phase is then washed at least once with a solution comprising an alkaline earth salt in a concentration ranging from 100mM to 240mM based on pH of 7 to 7.4 and the plasmid DNA bound to the chromatographic stationary phase is subsequently eluted with a solution comprising an alkali earth salt in a concentration of 270mM or higher based on pH 7 to 7.4 (see col. 3, line 6-54, col. 6, line 9-15).

With regard to claims 2-13, 18, Aberin et al. teach that the alkali salts comprise alkali halides and the solution for conductance, wash and elution solutions comprise KCl or NaCl at concentration ranging from 1.0 to 10 M based on pH 5 to 8.0 (see col. 3, line 6-54, col. 6, line 9-15).

With regard to claims 14-15, Aberin et al. teach that said chromatographic stationary phase is an anion exchanger that comprises hydroxyapatite (see col. 3, line 20-44).

With regard to claim 20-22, Aberin et al. teach nucleic acid mixture is a cleared lysate from prokaryotic cells and the method purifies plasmid DNA and the plasmid DNA is used for gene therapy or genetic vaccination (see col. 3, line 45-65, col. 1, line 11-54). Accordingly the instant claims are anticipated.

***Claim Rejections - 35 USC § 103***

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole

would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 16 is rejected under 35 U.S.C. 103(a) as being unpatentable over Thatcher et al. (US 5,981,735) in view of Colpan (US 5,990, 301).

Thatcher et al. teach a method for the chromatographic separation of nucleic acid mixture as discussed above in section 7A.

However Thatcher et al. did not teach preparing stationary phase.

Colpan et al. teach a method for purifying plasmid DNA wherein the method comprises preparation of the stationary phase, which enable packed diatomaceous useful in removal of endotoxins (see col. 7, line 9-67, col. 4, line 60-67, col. 5, line 1-67).

Therefore, it would have been prima facie obvious to a person of ordinary skill in the art at the time the invention was made, to combine the method as taught by Thatcher et al. with the step of preparation of stationary phase as prepared by Colpan et al. to achieve expected advantage of developing an improved and sensitive nucleic acid isolation method because method of preparing stationary phase as taught by Colpan et al. would result in efficient



separation of plasmid DNA with depleted endotoxin (see col. 7, line 9-67, col. 4, line 60-67, col. 5, line 1-67) and such a modification is considered obvious over the cited prior art.

***Conclusion***

No claims are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Suryaprabha Chunduru whose telephone number is 571-272-0783. The examiner can normally be reached on 8.30A.M. - 4.30P.M, Mon - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 571-272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Suryaprabha Chunduru/

Primary Examiner, Art Unit 1637

